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Henricks, Slavin & Holmes LLP  
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EXAMINER

VRETTAKOS, PETER J

ART UNIT PAPER NUMBER

3739

DATE MAILED: 06/19/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/045,669

Applicant(s)

PHAN, HUY D.

Examiner

Peter J Vrettakos

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4-9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### DETAILED ACTION

Claim 1 line 3 contains a typographical error. "Thermally" should read "thermal".

Correction is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 11-12, 15-21, 24-25 and 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaer in view of Swartz et al. ('654).

Note: Swartz et al. was disclosed by the Applicant in the IDS dated 6-19-02.

#### Independent claim 1

Schaer et al. (Schaer) discloses a soft tissue coagulation device (fig. 3), comprising:

a shaft (includes 28 and 64) defining a distal end and including an outer structure formed from material;

at least one energy transmission device (50) supported on the outer structure in spaced relation to the distal end of the shaft; and

at least one fluid lumen (32) defined by the outer structure and located such that a portion thereof is aligned with the at least one energy transmission device.

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Independent claim 15

Schaer et al. (Schaer) discloses a soft tissue coagulation device (fig. 3), comprising:

a shaft (includes 28 and 64) defining a distal end and including an outer structure formed from material;

at least one energy transmission device (50) supported on the outer structure in spaced relation to the distal end of the shaft; and

at least one fluid lumen (32) defined by the outer structure such that a wall (fig. 6a; 82) having a wall thickness is between the at least one fluid lumen and the at least one energy transmission device, located such that a portion thereof is aligned with the at least one energy transmission device, and including inner and outer surfaces defining a distance therebetween.

Schaer is silent with regards to the dimensions of the distance between inner and outer lumen surfaces, as well as wall thickness and which of the two is greater, as submitted in the last phrase of independent claim 15. *However*, these parameters (simple dimensions) could be determined through routine experimentation. In the event that the Applicant's disclosed parameters (qualitative) are optimal, then the parameters would be obvious in light of Schaer, especially figure 6a.

Independent claim 29

Schaer discloses a method comprising:

positioning the elongate transmission device in electrical contact with tissue;

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transmitting energy to the tissue with the energy transmission device; and  
passing fluid through the inner lumen such that heat is transferred from the  
energy transmission device to the fluid (through convection – see col. 14: 29-32; also  
see col. 21: 52-55).

Dependent claims

Re: claims 2 and 16, the breaks in the depicted shafts in figures 2, 7, and 11-15  
indicate that the length of the device is varying. Under this supposition, the Examiner  
contends that the shaft can be construed as being “relatively short”.

Re: claims 3 and 17, Schaer discloses a portion of the shaft that is relatively stiff  
(col. 12: 40-42).

Re: claims 4 and 18, Schaer discloses the use of a mandrel (col. 24: 30-34).

Re: claims 5 and 19, Schaer discloses a shaft that includes a tubular member  
(58) defining a distal end and the outer structure (64) extends distally from the distal end  
of the tubular member as depicted in figure 3.

Re: claims 6-7 and 20-21: Schaer depicts a steering apparatus for deflecting the  
distal portion in figure 14. Figure 14 also depicts a pre-bent portion in the shaft.

Re: claims 11, 12, 24-25, and 30, Schaer discloses a plurality of electrodes (fig.  
3, 52).

*Schaer, however, neglects to disclose a shaft made up of thermally conductive and  
electrically non-conductive material such as nylon (Application's Spec page 14:20-26).*

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Swartz et al. (Swartz) discloses an analogous electrosurgical catheter comprising a nylon shaft (col. 8: 34-42).

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Schaer in view of Swartz by using a *nylon* shaft (instead of Pebax, or an equivalent). The motivation would be to provide an alternate material choice for a shaft as well as to promote heat transfer to optimize surgical conditions.

Claims 8, 9, 10, 13-14, 22-23, 26-28, 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaer in view of Swartz and further in view of Maguire et al. ('854).

*Schaer and Swartz neglect to disclose an outflow lumen.*

Maguire et al. (Maguire) discloses an analogous electrode cooled probe in which inflow (50) and outflow lumens are implied ("recirculate") in col. 5: 47-49 that permit closed loop fluid cooling of the electrode. Also read col. 6:14-16 and col. 5:14-23.

Similarly to Schaer, Maguire is also silent with regards to the dimensions of the distance between inner and outer lumen surfaces, as well as wall thickness and which of the two is greater, as submitted in the last phrase of independent claim 15. *However*, these parameters (simple dimensions) could be determined through routine experimentation. In the event that the Applicant's disclosed parameters (qualitative) are optimal, then the parameters would be obvious in light of Maguire, especially figure 6a.

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Re: claims 14 and 27, Maguire discloses an analogous (to an outflow lumen) inner tubing (40) made of polyimide col. 4:33-36, which is a well-known thermal insulator.

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Schaer in view of Swartz and further in view of Maguire by including an outflow lumen thereby preventing saline or other fluids from exiting the probe onto the targeted tissue. The motivation to do so would be to provide a cooled electrode ablation device that can be used in surgical applications that might not require saline application on the tissue or that might be disadvantaged by saline application onto the targeted tissue, while still obtaining the advantages of preventing overheating as posited in Maguire col. 5:33-34.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Edwards et al. ('087) – see column 9:26-30.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J Vrettakos whose telephone number is 703 605 0215. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on 703 308 0994. The fax phone numbers

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for the organization where this application or proceeding is assigned are 703 746 7013 for regular communications and 703 746 7013 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 0858.

Pete Vrettakos  
June 13, 2003

*PV*

*Michael Peffley*  
MICHAEL PEFFLEY  
PRIMARY EXAMINER